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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,578	12/04/2000	Muriel Keller	BC-0181-P06	5244

24994 7590 09/10/2003

GAMBRO, INC
PATENT DEPARTMENT
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LAKEWOOD, CO 80215

EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

Office Action Summary

Application No.

09/729,578

Applicant(s)

KELLER ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,8 and 13-21 is/are rejected.
- 7) ☒ Claim(s) 3-6 and 9-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Response to Amendment

✓ 1. A preliminary amendment was filed December 14th, 2000. The specification was amended to claim priority under 35 USC 120. Claims 1-21 were amended and are currently pending.

Specification

✓ 2. Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

✓ 3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it includes the legal phraseology "**disclosed**." Correction is required. See MPEP § 608.01(b).

✓ 4. The disclosure is objected to because of the following informalities:

- (i) on page 122, line 12 the specification recites the phrase "*velocity during*" - it appears that a word was left out;
- (ii) on page 124, line 3 the phrase "*of the*" appears twice;
- (iii) on page 30, line 6 does applicant mean "*proceed*" or "*precede*"?

Appropriate correction is required.

Claim Rejections - 35 USC § 112

✓ 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 recites the phrase "***said set-up phase***" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 8, and 13-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Bischof (5,865,785). Bischof discloses a system and method of using the system for blood processing wherein whole blood is collected from a patient via a phlebotomized tubing flow path and delivered to a centrifuge for separation into its components (red blood cells (RBC), platelets, a buffy coat (WBC), and plasma). Bischof discloses that the system may be used in a continuous manner. It is well known that whole blood separates into its components upon centrifugation. It is well known that the difference in the densities of the blood components results in RBC being disposed at the radially outward most position, a buffy coat thereafter, and the plasma defining the innermost position. Platelets will be mainly in the buffy coat region. Therefore, since the Bischof system and method of using acts in a continuous manner, it is seen to be inherent that the whole blood will separate into RBC and platelets in a continuous manner since. As shown in the flow chart of figure 1, the RBC and platelets (PRP) are all separated and may be collected in separate containers. Bischof also teaches that plasma is separated and may be collected (see figure 2). The centrifuge or processing vessel inherently has a rpm rate for spinning and may be increased for spinning and separating the whole blood and decreased for collection.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **2, 20 & 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bischof in view of Latham, Jr. et al. (5,607,579). Bischof discloses the invention substantially as claimed, see rejection supra. Bischof, however, fails to disclose specifically that the hematocrit is at least 75%, an AC ratio of about 6-16 is established, and the hematocrit and AC ratio are maintained.

Latham, Jr. et al. teaches of a blood separation system and method where whole blood is separated in an apheresis method. The system includes sensors that determine the AC ratio (referred by Latham, Jr. to be ACD ratio) and a hematocrit percentage for optimum function. (Col. 3, line12-col. 5, line 63; figs. 8A-B). At the time

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of the invention, it would have been obvious to one having ordinary skill in the art to modify the system and method of Bischof to incorporate the sensors and steps of monitoring and maintaining the AC ratio and hematocrit to ensure the optimum treatment conditions for the patient/donor.

Allowable Subject Matter

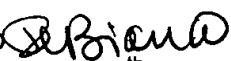
8. Claims 3-6 & 9-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb 
September 6th, 2003